Remarks

Claims 1-14, 18-34 and 36 are pending in the present application.

Claim 14 has been amended herein so as to recite "method using recombinant techniques" as suggested by the Examiner. See, Paper No. 13, page 8. Support for this amendment is found in claim 14 as originally filed. Accordingly no new matter has been introduced.

I. Rejections Under 35 U.S.C. § 112, first paragraph

A. Enablement

The Examiner rejects claims 1-14, 18-34 and 36, under 35 U.S.C. § 112, first paragraph, as allegedly containing "subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention essentially for the same reasons as set forth in the previous Office Action." *See*, Paper No. 13, pages 3-6.

More particularly, the Examiner alleges that:

> There does not appear to be sufficient guidance in the specification as filed as to how the skilled artisan would make the various nucleic acids recited in the instant claims. A person of skill in the art would not know which sequences are essential and which sequences are non-essential.
> ...
> there appears to be insufficient guidance in the specification as filed to direct a person of skill in the art to *select particular nucleotide sequence as encoding amino acids essential for the functional properties of the polypeptide. In addition, no functional properties of hPSP are even disclosed.*

See, Paper No. 13, page 4. The rejection is respectfully traversed.

Again Applicants assert that the present rejection is improperly based and that one reasonably skilled in the art, armed with the disclosure in the present specification coupled with information known in the art at the time the application was filed, could make and

use the claimed polynucleotides, without undue experimentation. Therefore the claimed polynucleotides are fully enabled within the meaning of 35 U.S.C. §112.

Preliminarily, Applicants respectfully point out that contrary to the Examiner's allegation the specification does indeed teach and suggest the use of the claimed polynucleotide in detecting the hPSP polypeptide expression in cancer diagnosis. *See*, Paper No. 13, page 3. For example, in the specification at page 33, lines 15-23, Applicants teach that "the invention provides a diagnostic method useful during diagnosis of a digestive, nonimmune defense, endocrine or immune system disorder, including cancers of these systems, which involves measuring the expression level of the gene encoding the hPSP protein." Furthermore, the specification teaches that one or more claimed polynucleotides may be used in the diagnosis of diseases of the digestive system and the non-immune defense of gastrointestinal mucosal surfaces. *See* e.g., Page 5, lines 28-32; Page 8, lines 27-30; Page 9, lines 22-28; and Page 32, line 20 through Page 37, line 12. Additionally, the specification teaches that use of the claimed nucleic acids as a nucleotide primer was routine and well within the abilities of those of ordinary skill in the relevant arts on the priority date of the present invention. *See e.g.*, Page 43, lines 8-19; Page 44, lines 16-29; Page 47, line 25 to Page 48 line 2; and Page 31, line 13 through page 32, line 16. Therefore, Applicants submit that the specification clearly and specifically teaches and suggests the use of the claimed invention.

The Examiner appears to require that Applicants enable the function of an hPSP polypeptide, when in actual fact it is only necessary to enable the detection of hPSP expression in colon and lung tumors. Applicants' respectfully point out that it is not necessary for the claimed polynucleotides, or any polypeptides encoded thereby, to be "biologically active" or to be defined by "functional properties," in order for them to be fully enabled. Rather, the claimed polynucleotides need merely have application in a

single use which is enabled by the specification as filed. In the instant application the nucleic acids of the invention have several uses asserted and enabled by the teachings of the specification as filed in the specification. These include use as an agent that hybridizes to other polynucleotides to detect expression of hPSP (*e.g.*, a primer or a probe). One of skill in the art would be capable of routinely using a polynucleotide of the claimed invention for such a purpose. For example, one or more claimed polynucleotides may be used in the diagnosis of diseases of the digestive system. *See* e.g., specification at Page 5, lines 28-32; Page 8, lines 27-30; Page 9, lines 22-28; and Page 32, line 20 through Page 37, line 12. Use of the claimed nucleic acids as a nucleotide primer was routine and well within the abilities of those of ordinary skill in the relevant arts on the priority date of the present invention. *See e.g.*, specification at Page 43, lines 8-19; Page 44, lines 16-29; Page 47, line 25 to Page 48 line 2; and Page 31, line 13 through page 32, line 16. Accordingly, Applicants contend that the claimed nucleic acids are enabled without any requirement for functional characterization of the hPSP polypeptide(s) encoded thereby, and that one of ordinary skill in the art would have been able to routinely make and use them commensurate with the scope of the claims.

Applicants assert that the Examiner has underestimated the level of skill of the skilled artisan and the teachings of the present specification. The skilled molecular biologist, enlightened by the teaching of the present specification, is more than capable of routinely determining whether a polynucleotide encompassed by the claims has uses commensurate in scope with the instant claims.

In view of the above remarks, Applicants believe the Examiner's concerns have been fully addressed. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-14, 18-34 and 36, under 35 U.S.C. § 112, first paragraph, for lack of enablement.

B. Written Description

The Examiner rejects claims 1-14, 18-20, 26-34 and 36, under 35 U.S.C. § 112, first paragraph, as allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention essentially for the same reasons as set forth in the previous Office Action. *See*, Paper No. 13, pages 6-8.

More specifically the Examiner alleges:

> the specification fails to provide sufficient guidance as to which core structure of SEQ ID NO:1 is essential to maintain its functional activity and which changes can be made in the structure of SEQ ID NO:1 and still maintained the same function.

See, Paper No. 13, page 6, lines 18-20.

Applicants respectfully disagree with the Examiner and submit that one skilled in the art could reasonably conclude that Applicants had possession of the polynucleotides encompassed by the rejected claims, in the present application as filed. Furthermore, Applicants submit that the Examiner has underestimated both the teaching of the present application and the level of skill in the art on the priority date of the present application.

As discussed above in relation to the statutory enablement requirement, it is not necessary for the claimed polynucleotides, or any polypeptides encoded thereby, to be "biologically active" or to be defined by "functional properties," in order for them to meet the written description requirements of 35 U.S.C. §112 ¶1. Indeed the claims as presently rejected do inevitably include polynucleotides which encode hPSP polypeptides lacking any biological function. However, the same polynucleotides may surely be used to detect hPSP expression and to diagnose cancers of the digestive system. Accordingly, Applicants contend that the claimed polynucleotides do receive adequate written

description support in the specification as filed, and that the instant rejections are improperly based.

It is well established that a "gene is a chemical compound, albeit a complex one". *Amgen, Inc. v. Chugai Pharamceutical Co., LTD.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Thus, the claims of the instant application, directed to particular polynucleotides of the disclosed nucleic acid sequence of SEQ ID NO:1, are essentially chemical claims involving generic chemical formulae. All of the objectives met by a generic chemical formula are similarly met by the explicit description in the instant specification of a polynucleotide sequence (*i.e.* SEQ ID NO:1) and the amino acid sequence encoded thereby (*i.e.*, SEQ ID NO:2). Accordingly, one skilled in the art would reasonably conclude that Applicants had possession of the polynucleotides encompassed by the rejected claims upon reading the present application as filed, and would immediately recognize that the Applicants had "invented what is claimed" (*Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). Therefore, the specification contains an adequate written description of the claimed polynucleotides. Applicants have provided the skilled artisan with a "generic formula" in the form of the nucleic acid sequence of SEQ ID NO:1, which indicates "with specificity what the generic claims encompass." Armed with this information "one skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass." Moreover, Applicants submit that one skilled in the art would be able to "visualize and recognize" innumerable members of the genus given the disclosure of the reference sequence common to all members of the genus. Indeed, the Written Description guidelines state:

> if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since

> the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence.

See, M.P.E.P. § 2163(II)(A)(3)(a)(ii) at 2100-165. Thus Applicants assert that the specification has satisfied the requirements for written description as set forth in *Eli Lilly & Co. (University of California v. Eli Lilly*, 119 F.3d 1559 (Fed. Cir. 1997)). Accordingly, Applicants respectfully request that this rejection be withdrawn.

In light of the above, Applicants respectfully assert that the Examiner has failed to meet the required burden in presenting evidence or reasons why those skilled in the art would not recognize the claimed invention from the disclosure. Moreover, the specification conveys with reasonable clarity that Applicants were in possession of the claimed invention. Therefore, Applicants submit that the pending claims fully meet the written description requirements of 35 U.S.C. § 112, first paragraph, and respectfully request that the Examiner's rejection of the claims under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

In light of these clarifications, Applicants respectfully request that the Examiner's rejection of claims 1-14, 18-20, 26-34 and 36, under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

III. Rejection Under 35 U.S.C. § 112, second paragraph

The Examiner rejects claim 14 under 35 U.S.C. § 112, second paragraph as allegedly being "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." *See*, Paper No. 13, page 8. Applicants respectfully disagree and traverse these rejections.

The Examiner alleges that it is unclear what is meant by the terms "recombinant method." Applicants respectfully suggest that the term "recombinant method" has a generally accepted meaning within the art, which may be thought of as approximately the same as "a method using recombinant techniques."

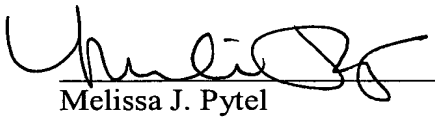
Applicants point out that claim 14 has been amended herein so as to recite "method using recombinant techniques," thereby obviating the instant rejection. Accordingly, Applicants respectfully request that the Examiner's rejection of claim 14 under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

Conclusion

Applicants respectfully request that the remarks of the present response be entered and made of record in the present application. The present application is believed to be in condition for allowance. Early notice to that effect is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution, the undersigned can be reached at the telephone number indicated below. If a fee is required in connection with this paper, please charge Deposit Account No. 08-3425 for the appropriate amount.

Respectfully submitted,

Dated: May 14, 2003



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